

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification requirements in part 807, subpart E of this chapter if it is sold, distributed, and used in accordance with the restrictions set forth in § 809.40 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.198, with respect to complaint files.

Dated: September 25, 1997.

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 98-5521 Filed 3-3-98; 8:45 am]

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NATIONAL INDIAN GAMING COMMISSION

25 CFR Chapter III

Minimum Internal Control Standards for Gaming Operations for Indian Lands

AGENCY: National Indian Gaming Commission.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: This document announces the initiation of the rulemaking process and requests information relevant to implementing regulations governing minimum internal control standards for gaming operations operated on Indian lands. The Commission has determined that minimum internal control standards are needed to ensure the integrity of gaming on Indian lands and to safeguard this source of tribal revenues.

DATES: Comments in response to this advance notice must be submitted by April 5, 1998. The Commission will be holding a hearing on this matter on April 1, 1998, in Portland, Oregon.

ADDRESSES: Commentors may submit their comment by mail, facsimile, or delivery to: Minimum Internal Control Rule Comments, National Indian Gaming Commission, Suite 9100, 1441 L Street N.W., Washington, DC 20005. Fax number: 202-632-7066 (not a toll-free number). Public comments may be delivered or inspected from 9 a.m. until noon and from 2 p.m. to 5 p.m. Monday through Friday.

The public hearing will be held at the Doubletree Hotel at Lloyd Center, Portland, Oregon.

FOR FURTHER INFORMATION CONTACT: Mia Dinh at 202-632-7003, or by facsimile at 202-632-7066 (not toll-free numbers.)

SUPPLEMENTARY INFORMATION:

1. Introduction

The Indian Gaming Regulatory Act (IGRA, or the Act), 25 U.S.C. 2701 *et seq.*, was signed into law on October 17, 1988. The Act established the National Indian Gaming Commission (the Commission). The IGRA was enacted for several purposes, primary among them was to provide a statutory basis for the operation of gaming by Indian tribes as a means of promoting economic development self-sufficiency and strong tribal governments, as well as to provide for the regulation of gaming by Indian tribes adequate to shield them from organized crime. The Commission has determined that minimum internal control standards are needed to ensure the integrity of gaming on Indian lands and to safeguard this source of tribal revenues.

The IGRA expressly authorizes the Commission to "promulgate such regulations and guidelines as it deems appropriate to implement the provision of this [Act]." 25 U.S.C. 2706(b)(10).

2. Advance Notice of Proposed Rulemaking

After consideration of this issue, the NIGC has determined that the appropriate course of action is to publish an Advance Notice of Proposed Rulemaking to collect further information.

Before the NIGC proceeds in this area, it intends to have the benefit of a full airing of the issues through the public comment process.

3. Request for Comments

Public comment is requested to assist the NIGC in the drafting of minimum internal control regulations. Comment is requested on the following issues:

(a) Should standards be tiered based on the physical size of the operation, the amount of the gross revenues derived from gaming, or some other criteria? Please explain.

(b) If yes, what tiers should be adopted. Please explain.

(c) What standards should apply to all operations and what standards should apply to only one or two tiers and not the others?

(d) What are the major internal control issues/problems that Indian gaming operations face?

(e) How long should the Commission allow the tribes to implement internal controls that would comply with the regulations?

The Commission solicits any additional suggestions and/or interpretations regarding the issues raised in this Advance Notice of Proposed Rulemaking.

4. Public Participation

Interested parties are invited to submit comments on any or all of these and other pertinent issues related to minimum internal control regulations by April 5, 1998, in triplicate to Minimum Internal Control Rule Comments, National Indian Gaming Commission, Suite 9100, 1441 L Street N.W., Washington, DC 20005. Fax number: 202-632-7066 (not a toll-free number). All written comments submitted in response to this notice will be available for inspection and copying in the NIGC office from 9 a.m. until noon and from 2 p.m. to 5 p.m. Monday through Friday. All timely written submissions will be considered in determining the nature of any proposal.

Authority and Signature

This Advance Notice of Proposed Rulemaking was prepared under the direction of Larry Rosenthal, Chief of Staff, National Indian Gaming Commission, 1441 L St. N.W., Suite 9100, Washington, DC 20005.

Signed at Washington, D.C. this 27th day of February, 1998.

Larry Rosenthal,

Chief of Staff, National Indian Gaming Commission.

[FR Doc. 98-5656 Filed 3-4-98; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[REG-209276-87]

RIN 1545-AV32

Abatement of Interest; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to notice of proposed rulemaking.

SUMMARY: This document contains a correction to REG-209276-87, which was published in the **Federal Register** on Thursday, January 8, 1998 (63 FR 1086), relating to the abatement of interest attributable to unreasonable errors or delays by an officer or employee of the IRS.

FOR FURTHER INFORMATION CONTACT: David Auclair, (202) 622-4910 (not a toll-free number).